

CLAIMS

1. A method for detecting, in liver tissue isolated from a human subject and suspected of being cancerous, 5 integration of HBV-DNA into the MLL4 gene, said integration of HBV-DNA indicating cancerous nature of a tissue.

2. The method according to claim 1, for detecting integration of HBV-DNA into the MLL4 gene by 10 conducting a polymerase chain reaction (PCR) on DNA from the liver tissue; and confirming the integration of HBV-DNA into the MLL4 gene by determining the base sequence of the amplified DNA.

3. The method according to claim 2, wherein the integration of a region containing the HBV-DNA X gene into 15 intron 3 of the MLL4 gene is confirmed.

4. The method according to claim 1, for detecting the integration of HBV-DNA into intron 3 of the MLL4 gene.

5. The method according to claim 4, for detecting the integration of HBV-DNA into the region of intron 3 of the MLL4 20 gene from base number 17515 to 17818 from the 5' end.

6. The method according to claim 1, 4, or 5, wherein the HBV-DNA is a region containing the X gene of HBV.

7. A method for detecting, in liver tissue isolated from a human subject and suspected of being cancerous, 25 integration of HBV-DNA into the MLL4 gene, said integration of

HBV-DNA indicating the cancerous nature of a tissue, by a procedure comprising the steps of:

(1) extracting DNA from the liver tissue;

(2) carrying out PCR using, with the DNA obtained in (1)

5 being used as template, a first primer specific to the region containing intron 3 of the MLL4 gene and a first primer specific to the X gene region of HBV; and

(3) optionally carrying out PCR again using ,with the DNA amplified in (2) being used as template, a second primer 10 specific to the region containing intron 3 of the MLL4 gene and a second primer specific to the X gene region of HBV.

8. The method according to any of claims 1, 4, 5, and 6, wherein integration of HBV-DNA into the MLL4 gene is detected by detecting an MLL4 gene/HBV fusion transcription product.

15 9. The method according to claim 8, for detecting an MLL4 gene/HBV X region fusion transcription product.

10. The method according to any of claims 1, 4, 5, and 6, wherein integration of HBV-DNA into the MLL4 gene is detected by detecting an MLL4/HBV fusion protein.

20 11. The method according to claim 10, comprising detecting an MLL4/HBV X region fusion protein.

12. The method according to claim 10 or 11, which uses an antibody or antibody fragment that specifically binds to an MLL4/HBV X region fusion protein.

25 13. A method for detecting, in liver tissue isolated from a human subject and suspected of being cancerous, a

t(17;19) (p11.2;q13.1) chromosomal translocation of the MLL4 gene, said translocation indicating the cancerous nature of a tissue.

14. The method according to claim 13, for detecting the
5 t(17;19) (p11.2;q13.1) chromosomal translocation of the MLL4 gene by detecting a base sequence that includes a junction between chromosome 17 and chromosome 19.

15. The method according to claim 14, for detecting a base sequence containing a junction between chromosome 17 and
10 chromosome 19 by a procedure comprising the steps of:

- (1) extracting DNA from the liver tissue;
- (2) carrying out PCR using, with the obtained DNA being used as template, a first primer specific to a region containing p11.2 of chromosome 17 and a first primer specific
15 to a region containing intron 3 of the MLL4 gene at q13.1 of chromosome 19; and
- (3) carrying out PCR using, with the amplified DNA being used as template, a second primer specific to the region containing p11.2 of chromosome 17 and a second primer specific
20 to the region containing intron 3 of the MLL4 gene at q13.1 of chromosome 19.

16. A kit for detecting the integration of HBV-DNA into the MLL4 gene.

17. A kit for detecting the integration of HBV-DNA into
25 intron 3 of the MLL4 gene.

18. A kit for detecting the integration of the X region of HBV into intron 3 of the MLL4 gene.

19. The kit according to claim 18, comprising a primer or probe specific to the region containing intron 3 of the
5 MLL4 gene and a primer or probe specific to the X region of HBV.

20. A kit for detecting an MLL4 gene/HBV X region fusion transcription product.

21. A kit for detecting an MLL4 gene/HBV X region fusion
10 protein.

22. The kit according to claim 21, comprising an antibody or antibody fragment that specifically binds to an MLL4/HBV X region fusion protein.

23. A kit for detecting a t(17;19) (p11.2;q13.1)
15 chromosomal translocation of the MLL4 gene.

24. The kit according to claim 23, comprising a primer or probe specific to the region containing intron 3 of the MLL4 gene and a primer or probe specific to the region containing p11.2 of chromosome 17.